

Attorney General Jennings Announces Multistate Settlement with C.R. Bard

Attorney General Jennings announced Friday a settlement by 48 states and the District of Columbia with C.R. Bard, Inc. and its parent company Becton, Dickinson and Company for the deceptive marketing of transvaginal surgical mesh devices. The settlement follows a [2019 settlement with Johnson & Johnson Ethicon, Inc.](#) for similar conduct.

Surgical mesh is a synthetic knitted or woven fabric that is permanently implanted in the pelvic floor through the vagina to treat pelvic organ prolapse and stress urinary incontinence. These are common conditions faced by women due to a weakening in their pelvic floor muscles caused by childbirth, age, and other factors.

Thousands of women implanted with surgical mesh have made claims that they suffered serious complications resulting from these devices, including erosion of mesh through organs, pain during sexual intercourse, and voiding dysfunction. Although use of surgical mesh involves the risk of these complications and is not proven to be more effective than traditional tissue repair, millions of women were implanted with these devices.

The attorneys general allege that C.R. Bard misrepresented or failed to adequately disclose serious and life-altering risks of surgical mesh devices, such as chronic pain, scarring and shrinking of bodily tissue, painful sexual relations, and recurring infections, among other complications.

“Manufacturers of medical devices must do better than the cavalier and dangerous attitude towards women exhibited by C.R. Bard, Becton, Dickinson and Company and others in the surgical mesh market,” said Attorney General Jennings.

“Today’s settlement holds C.R. Bard and Becton, Dickinson and Company accountable for their failures. As I promised in 2019, my office will continue to ensure that Delawareans can rely on manufacturer’s assurances as to the safety and effectiveness of medical devices.”

Although C.R. Bard stopped selling transvaginal mesh, the settlement provides injunctive relief requiring both C.R. Bard and Becton, Dickinson and Company to adhere to certain injunctive terms if they reenter the transvaginal mesh market.

Under the terms of the settlement, the companies are required to:

- Provide patients with understandable descriptions of complications in marketing materials.
- Include a list of certain complications in all marketing materials that address complications.
- Disclose complications related to the use of mesh in any training provided that includes risk information.
- Disclose sponsorship in clinical studies, clinical data, or preclinical data for publication.
- Refrain from citing to any clinical study, clinical data, or preclinical data regarding mesh, for which the company has not complied with the disclosure requirements.
- Require consultants to agree to disclose in any public presentation or submission for publication Bard’s sponsorship of the contracted for activity.
- Register all Bard-sponsored clinical studies regarding mesh with ClinicalTrials.gov.
- Train independent contractors, agents, and employees who sell, market, or promote mesh regarding their obligations to report all patient complaints and adverse events to the company.
- Ensure that its practices regarding the reporting of patient complaints are consistent with FDA requirements.

C.R. Bard and its parent company, Becton, Dickinson and Company, have agreed to pay \$60 million to the 48 participating states and the District of Columbia. Delaware will receive \$629,093.00 under the settlement which will go to the state's Consumer Protection Fund.

The matter was handled for Delaware by Deputy Director of Consumer Protection Regina S. Schoenberg.